



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 480-3387

April 10, 2020

Re: Animal Welfare Assurance  
A3205-01 [OLAW Case J]

Dr. Sheila Garrity  
Executive Director  
Research Integrity and Compliance  
George Washington University  
2121 Eye Street, N.W., (b) (4)  
Washington, DC 20052

Dear Dr. Garrity,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 4, 2020 letter amending a previous report of a suspension of an animal activity at George Washington University. According to the information provided, OLAW understands that at a convened meeting of the Institutional Animal Care and Use Committee (IACUC), the quorum voted unanimously to lift the suspension of the protocol.

OLAW concurs with the action taken by the IACUC. I had also asked for confirmation that the suspension had been reported to the NIH funding components. Please have (b) (6) respond in a brief email that this has been completed. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair

March 6, 2020

Axel Wolff, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892

Dear Dr. Wolff:

The George Washington University (GWU), in accordance with Assurance D16-00128 (formerly A3205-01) and PHS Policy IV.F.3., provides this report of non-compliance regarding the suspension of an IACUC protocol.

At a full committee meeting on December 13<sup>th</sup>, 2019, the IACUC was reviewing a de novo for a protocol. While discussing the submission, the committee was notified that the lab did not have an approved Institutional Biosafety Committee (IBC) protocol, despite the BSL-2 work (injection of human cell lines) described within the IACUC protocol. Additionally, it was noted that the lab was not following the proper procedures for the use of chemical hazards within the vivarium. For the safety of the laboratory staff, as well as the animal care technicians, the IACUC voted to **suspend** the animal protocol until the following items were completed:

- *The IBC protocol must be approved.*
- *All animal users within the lab must meet with the Director of the Office of Animal Research (OAR), to discuss the OAR's standard operating procedures for the use of BSL-2 agents, and hazardous chemicals.*

The protocol in question is currently funded by NIAAA grant number 5-R01-AA023146-14 and NCI grant number 5-R01-CA236591-02.

The following corrective action plan was implemented after the suspension:

1. On the date of suspension, all animals on the protocol were transferred to a holding protocol under the Attending Veterinarian.
2. On December 20<sup>th</sup>, 2019, the PI notified the IACUC that the IBC protocol was approved. The IACUC Administrator confirmed this approval through the IBC office.

3. On December 20<sup>th</sup>, 2019, the PI also notified the IACUC that the laboratory staff met with the Director of the OAR to discuss the facility SOPs for working under BSL-2 conditions and using chemical hazards. The discussion included the use of proper signage, methods of containment, access to N95 respirators, and the disposal of hazardous items.
4. The OAR worked with the lab to relocate all mouse cages that had been exposed to hazardous chemicals to the BSL-2 suite. The necessary PPE was provided, and signage was placed on the cages as well as the door to the holding room to indicate the hazards in use.
5. On December 26<sup>th</sup>, 2019, the IACUC was provided an update of the situation and asked to vote electronically regarding whether to lift the suspension of the protocol.
6. On January 3<sup>rd</sup>, 2020, the votes were tallied and the IACUC approved the protocol, thus lifting the suspension.
7. All mice were transferred back to the investigator's protocol from the holding protocol.

The George Washington University is committed to protecting the welfare of animals used in research, as well as the individuals that work directly with these animals, and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact [REDACTED] (b) (6) at ([iacuc@gwu.edu](mailto:iacuc@gwu.edu)).

Thank you for your consideration of this matter.

Sincerely,

**Sheila R.  
Garrity**

Digitally signed by Sheila R. Garrity  
DN: cn=Sheila R. Garrity, o=The  
George Washington University,  
ou=Office of the Vice President for  
Research,  
email=srgarrity@gwu.edu, c=US  
Date: 2020.04.09 18:20:07 -04'00'

Sheila Garrity, JD, MPH, MBA  
Institutional Official  
Associate Vice President for Research Integrity  
The George Washington University

Addendum: April 4<sup>th</sup>, 2020

Dear Dr. Wolff:

The George Washington University (GWU) submits this addendum to the report of non-compliance initially sent to OLAW on March 6<sup>th</sup>, 2020.

The IACUC reviewed (b) (6) protocol via Designated Member Review (DMR). At a convened meeting with a quorum, there was a majority vote to suspend the protocol. The IACUC continued to process the submission via DMR after the suspension. Once all of the IACUC's concerns were addressed, the designated reviewer submitted his/her recommendation to approve the protocol and lift the suspension.

As an extra precaution, at a convened meeting with a quorum on March 10<sup>th</sup>, 2020, the IACUC voted unanimously to lift the suspension of (b) (6) protocol.

The George Washington University is committed to protecting the welfare of animals used in research, as well as the individuals that work directly with these animals, and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact (b) (6) at (iacuc@gwu.edu).

Thank you for your consideration of this matter.

Sincerely,

Sheila R.  
Garrity

Digitally signed by Sheila R. Garrity  
DN: cn=Sheila R. Garrity, o=The  
George Washington University,  
ou=Office of the Vice President for  
Research,  
email=srgarrity@gwu.edu, c=US  
Date: 2020.04.09 19:11:13 -04'00'

Sheila Garrity, JD, MPH, MBA  
Institutional Official  
Associate Vice President for Research Integrity  
The George Washington University

## Wolff, Axel (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, April 10, 2020 7:15 AM  
**To:** iacuc  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: OLAW Case A3205-J

Thank you for this amended report, (b) (6) We will send a reply soon.  
Axel Wolff

**From:** iacuc <iacuc@email.gwu.edu>  
**Sent:** Thursday, April 9, 2020 7:19 PM  
**To:** Walker, Keri (NIH/OD) [C] <keri.walker@nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** srgarrity@gwu.edu; (b) (6)  
**Subject:** RE: OLAW Case A3205-J

Dear Dr. Walker,

In response to Dr. Wolff's letter, the George Washington University (GWU), would like to provide an addendum to the report of non-compliance initially submitted on March 6, 2020.

Please acknowledge receipt of this report.

Sincerely,

(b) (6)

**From:** Walker, Keri (NIH/OD) [C] <keri.walker@nih.gov>  
**Sent:** Wednesday, March 11, 2020 11:20 AM  
**To:** [srgarrity@gwu.edu](mailto:srgarrity@gwu.edu)  
**Cc:** [iacuc@gwu.edu](mailto:iacuc@gwu.edu)  
**Subject:** OLAW Case A3205-J

Dear Dr. Garrity,

Attached please find Dr. Wolff's response to OLAW Case A3205-J.

If you have any questions, feel free to contact us by phone or by e-mail.

Best Regards,  
Keri

*Keri Walker  
Program Specialist (Contractor)  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6700B Rockledge Dr., Suite 2500  
Bethesda, MD 20892  
301-435-2390  
[keri.walker@nih.gov](mailto:keri.walker@nih.gov)*





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March 11, 2020

Re: Animal Welfare Assurance  
A3205-01 [OLAW Case J]

Dr. Sheila Garrity  
Executive Director  
Research Integrity and Compliance  
George Washington University  
2121 Eye Street, N.W., (b) (4)  
Washington, DC 20052

Dear Dr. Garrity,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 6, 2020 letter reporting the suspension of an animal activity at George Washington University, following up on an initial telephone report on December 19, 2019. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) took this action after determining that a Biosafety Level 2 (BSL-2) study did not have approval from the Institutional Biosafety Committee (IBC) and that laboratory staff was not handling chemical hazards appropriately.

The corrective action consisted of suspending the protocol, transferring the mice to a holding protocol, having the IBC approve the protocol, counseling the laboratory staff on safety procedures, moving mouse cages exposed to chemical hazards to a BSL-2 room, having the laboratory acquire personal protective equipment, placing hazard labels on the cages and room door, having the IACUC approve the protocol and lift the suspension, and transferring the mice back to the protocol.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. While OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy on Humane Care and Use of Laboratory Animals, we note that the lifting of the suspension by electronic vote is not compliant. This action must be conducted in accordance with IV.C.2 of the PHS Policy, just as for a new protocol. Guidance on the use of telecommunications for IACUC meetings is attached <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-052.html>. Please conduct the review of this protocol as described and notify me by **April 10, 2020** that this was done and confirm that the NIH funding components had been notified about the suspension. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair

March 6, 2020

Axel Wolff, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892

Dear Dr. Wolff:

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- *The IBC protocol must be approved.*
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2. On December 20<sup>th</sup>, 2019, the PI notified the IACUC that the IBC protocol was approved. The IACUC Administrator confirmed this approval through the IBC office.



3. On December 20<sup>th</sup>, 2019, the PI also notified the IACUC that the laboratory staff met with the Director of the OAR to discuss the facility SOPs for working under BSL-2 conditions and using chemical hazards. The discussion included the use of proper signage, methods of containment, access to N95 respirators, and the disposal of hazardous items.
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6. On January 3rd, 2020, the votes were tallied and the IACUC approved the protocol, thus lifting the suspension.
7. All mice were transferred back to the investigator's protocol from the holding protocol.

The George Washington University is committed to protecting the welfare of animals used in research, as well as the individuals that work directly with these animals, and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact (b) (6) at (iacuc@gwu.edu).

Thank you for your consideration of this matter.

Sincerely,

Sheila R.  
Garrity

Digitally signed by Sheila R. Garrity  
DN: cn=Sheila R. Garrity, o=The George  
Washington University, ou=Office of  
the Vice President for Research,  
email=srgarrity@gwu.edu, c=US  
Date: 2020.03.06 13:35:20 -05'00'

Sheila Garrity, JD, MPH, MBA  
Institutional Official  
Associate Vice President for Research Integrity  
The George Washington University

**Morse, Brent (NIH/OD) [E]**

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, March 10, 2020 3:59 PM  
**To:** iacuc; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Sheila Garrity; phernand@gwu.edu  
**Subject:** RE: GWU - IACUC Suspension - Final Report

Thank you for providing this report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

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**From:** iacuc <iacuc@email.gwu.edu>  
**Sent:** Friday, March 06, 2020 3:40 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Sheila Garrity <srgarrity@email.gwu.edu>; (b) (6)  
**Subject:** GWU - IACUC Suspension - Final Report

Dear Dr. Wolff,

The George Washington University (GWU), in accordance with Assurance D16-00128 (formerly A3205-01) and PHS Policy IV.F.3., provides this report of non-compliance regarding the suspension of an IACUC protocol.

Please acknowledge receipt of this report.

Sincerely,

(b) (6)





## Initial Report of Noncompliance

By: aw

Date: 12/19/19

Time: 2:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: George Washington

Assurance number: A3205

Did incident involve PHS funded activity? Yes

Funding component: NIHAA-NC

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

Didn't get IBC approval to work w/ Hazardous chemicals  
+ human cells

Species involved: Mouse

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

Suspend protocol until IBC in place + get  
safety procedures in place. Signs, PPE.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_